

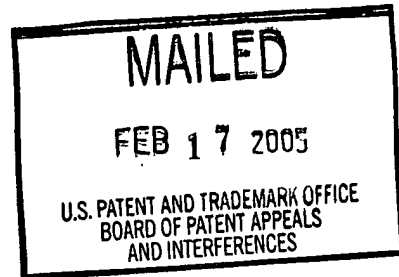
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARIO BIGAZZI

Appeal No. 2005-0389
Application No. 09/606,569

ON BRIEF



Before WILLIAM F. SMITH, ELLIS, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-5. The only other pending claim, claim 6, has been withdrawn from consideration as a result of a restriction requirement. Brief, page 2.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. Method of treating a Th2-dominated disease in a human patient exhibiting said disease, comprising administering to the patient an effective amount of relaxin or derivative thereof for relieving said disease.

The references relied upon by the examiner are:¹

Masini et al. (Masini), "Relaxin inhibits histamine release from mast cells: Involvement of nitric oxide production," Inflammation Research, Vol. 44, Suppl. 1, pp. S12-S13 (1995)

Bani et al. (Bani), "Relaxin Counteracts Asthma-Like Reaction Induced by Inhaled Antigen in Sensitized Guinea Pigs," Endocrinology, Vol. 138, No. 5, pp. 1909-1915 (1997)

GROUND OF REJECTION

Claims 1-5 stand rejected under 35 U.S.C. § 103. As evidence of obviousness the examiner relies on Bani and Masini².

We affirm.

CLAIM GROUPING

According to appellant (Brief, page 4), the claims stand or fall separately. We note however, that appellant's only statement with regard to claims 1-5 appears at page 11 of the Brief, wherein appellant recites the limitations of each claim. A recitation of the claim limitations is not a separate argument as to the claim as required by 37 CFR § 1.192(c)(7) (2003) (Claims stand or fall together

¹ We recognize the examiner's reliance on:

DeKruyff et al. (DeKruyff)

6,086,898

Jul. 11, 2000

Piccinni et al. (Piccinni), "Environmental Factors Favoring the Allergen-specific Th2 Response in Allergic Subjects," Neuroimmunomodulation, Vol. 917, pp. 844-852 (2000)

These references, however, were not made of record in the Final Office Action, dated June 17, 2003, and appear to have been relied upon for the first time in the Answer. As set forth in In re Hoch, 428 F.2d 1341, 1342 n.3, 166 USPQ 406, 407 n.3 (CCPA 1970) ("[w]here a reference is relied on to support a rejection, whether or not in a 'minor capacity,' there would appear to be no excuse for not positively including the reference in the statement of the rejection"). Accordingly, these references do not appear to be properly before us for review, and we have not considered them in our deliberations.

"unless a statement is included that the claims of a group do not stand or fall together and, in the argument under paragraph (C)(8) of this section, appellant explains why the claims of the group are believed to be separately patentable. Merely pointing out differences in what the claims cover is not an argument as to why the claims are separately patentable.").

Therefore, the claims on appeal are considered to stand or fall together. Since all claims stand or fall together, we limit our discussion to representative independent claim 1. Claims 2-5 will stand or fall together with claim 1. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

DISCUSSION

According to the examiner (Answer, page 5), Bani "teach that relaxin (RLX) counteracts the respiratory and histopathological abnormalities of an experimentally induced asthma like reaction in guinea pigs." The examiner finds (id., emphasis added), Bani "teach that in the guinea pig, repeated exposure to antigen has been demonstrated to cause airway hyper-responsiveness and leukocyte infiltration of lung tissue mimicking histological and pharmacological correlates of asthma in humans." In addition, the examiner finds (Answer, page 6-7), Bani teach "that the study provides evidence for an anti-asthmatic property

² We find Masini to be commutative to the teachings of Bani, therefore we limit our discussion to the Bani reference.

of RLX and raises the possibility of new therapeutic strategies for allergic asthma^[3] in humans using RLX (abstract)."

While Bani does not teach the administration of RLX to humans as is required by appellant's claimed invention, the examiner finds (Answer, page 6-7), it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to follow the teachings of Bani to treat a human suffering from allergic asthma – a Th2-dominated disease. According to the examiner (Answer, page 6), Bani provides not only the motivation, but also a reasonable expectation of success in treating allergic asthma in humans, because Bani demonstrate that RLX can be used to treat allergic asthma in guinea pigs that mimic histological and pharmacological correlates of asthma in humans.

In response, appellant presents two major arguments; (1) Bani does not discuss asthma in terms of a Th2-dominated disease, but instead Bani teach a different mechanism based on the production of nitric oxide (NO) (see e.g., Brief, page 8); and (2) Bani merely raises the possibility of the use of RLX to treat asthma in humans (see e.g., Brief, page 10). We will discuss each in turn.

1. Bani's use of RLX is mechanistically different from the claimed invention:

There is no dispute on this record that asthma as taught by Bani is a Th2-dominated disease. See Answer, page 6; Brief, page 8. There is also no

³ The examiner asserts (Answer, page 6), "[a]sthma is a Th2 dominated disease, which elicits a pathogenic Th2 response." Appellant does not dispute this assertion. To the contrary, appellant confirms that "asthma is a species of a Th2-dominated disease genus...." Brief, page 8.

dispute that Bani teach the use of RLX to successfully treat experimentally-induced asthma in guinea pigs. See e.g., Answer, page 5; Brief, page 8. There is no showing on this record that the guinea pig model of asthma is not a Th2-dominated disease.⁴ To the contrary, Bani teach that “in the guinea pig, repeated exposure to antigen has been demonstrated to cause airway hyperresponsiveness and leukocyte infiltration of lung tissue mimicking histological and pharmacological correlates of asthma in humans....”⁵ Bani, last paragraph of introduction, endnotes omitted.

Here, appellant appears to provide a different scientific explanation, than Bani, for the function of RLX in the treatment of asthma, specifically that by treating asthma RLX treats a Th2-dominated disease. In our opinion, such a revision of the underlying mechanism through which RLX acts does not tip the scale in favor of patentability. Cf. Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999) (“The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate.”).

⁴ Accordingly, we are not persuaded by appellant's assertion (Brief, page 9, emphasis removed), “[t]here is no art taught equivalency between ... guinea pig based RLX experiments and human based RLX experiments in general....” We remind appellant that argument of counsel cannot take the place of objective evidence on the record. In re Payne, 606 F.2d 303, 315, 203 USPQ 245, 256 (CCPA 1979); Meitzner v. Mindick, 549 F.2d 775, 782, 193 USPQ 17, 22 (CCPA 1977); In re Lindner, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972). We accord such argument little or no evidentiary weight.

⁵ Accordingly, we are not persuaded by appellant's argument (Brief, page 12), “no art established equivalency has been set forth by the [e]xaminer as between guinea pigs and human beings....”

Accordingly, we are not persuaded by appellant's argument that Bani's use of RLX is mechanistically different from the claimed invention.

2. Does Bani provide a reasonable expectation of success?

Appellant asserts (Brief, bridging paragraph, pages 9-10, emphasis removed), Bani did not say that RLX is useful to treat asthma in human beings, but rather that the results taught by Bani raise the possibility of new therapeutic strategies for allergic asthma in humans. According to appellant (Brief, page 16), "Bani ... at best alone or in combination present[s] a speculative invitation to experiment to see whether the raised possibility that RLX may be able to treat asthma in human beings is actually correct or incorrect." Appellant argues (Reply Brief, page 3), Bani "also raises the equal possibility that RLX may not be so used. Such is not motivation to carry out the invention with an expectation of success but rather a speculative invitation to experiment in the empirical and unpredictable medical arts."

As discussed above, there is no dispute on this record that asthma is a Th2-dominated disease, or that Bani demonstrate that RLX can be successfully used to treat experimentally-induced asthma in a guinea pig model that mimics histological and pharmacological correlates of asthma in humans. Further, according to Bani (abstract), "[t]his study provides evidence for an antiasthmatic property of RLX and raises the possibility of new therapeutic strategies for allergic asthma in humans." From Bani, what is left for a person of ordinary skill

in the art⁶ to do, but to move forward with a treatment of allergic asthma in humans? In this regard, we remind appellant, as set forth in In re O'Farrell, 858 F.2d 894, 904, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988), citations omitted:

obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious. ... For obviousness under §103, all that is required is a reasonable expectation of success.

In our opinion, the information in the Bani reference provides a reasonable expectation of success for treating asthma (a Th2-dominated disease) in a human patient, comprising administering to the patient an effective amount of relaxin for relieving said disease.

We recognize appellant's assertion (Reply Brief, page 6), Cronin⁷ and Bigazzi-296⁸ "vitate any [e]xaminer asserted expectation of success." According to appellant (Brief, page 14), "Cronin emphasizes the unpredictability as to medical uses of RLX in regard to various therapies there discussed, and the confusing results as to given medical uses that have been obtained therewith." Appellant, however, fails to identify where Cronin discusses asthma.

⁶ As set forth in Life Tech., Inc. v. Clontech Labs., Inc., 224 F.3d 1320, 1326, 56 USPQ2d 1186, 1191 (Fed. Cir. 2000), a "[r]easonable expectation of success is assessed from the perspective of one of ordinary skill in the art" at the time the invention was made.

⁷ Cronin et al. (Cronin) 5,166,191 Nov. 24, 1992

⁸ Bigazzi 5,952,296 Sep. 14, 1999

Nevertheless, Cronin discloses (col. 4, lines 20-25), "[t]here are sporadic reports on the effect of relaxin administration on blood vessels, and blood pressure under special circumstances, without any written indication that the reported observations could have any potential therapeutic implications." The remainder of column 4 of Cronin discloses various observations on the effect of relaxin on blood vessels and blood pressure. According to Cronin (col. 5, lines 1-2), "[i]n view of these contradictory findings, the effect of relaxin on arterial pressure is at best unclear." The remainder of the patent discloses the results of Cronin's studies, resulting in claims to a method for increasing cardiac output by administering relaxin to a patient. Contrary to appellant's assertion, in our opinion, Cronin (which issued 8 years prior to the filing date of the instant invention) supports the examiner's position that Bani provides a reasonable expectation of success.

Bigazzi (also the inventor of the instant invention), issued less than a year prior to the filing date of the present invention. According to appellant (Brief, page 14), Bigazzi emphasizes "the unpredictability of its [(relaxin's)] therapeutic use due to its dose-dependency...." Upon review of the cited section of Bigazzi, contrary to appellant's assertion, Bigazzi teaches the use of relaxin in pathological situations which are due to histamine liberation such as allergic rhinitis, bronchial asthma, etc. As to appellant's assertion that Bigazzi emphasizes a dose-dependency, according to Bigazzi (col. 9, lines 23-24), "[t]he degree of [histamine] inhibition was the function of the dose of relaxin being used."

While appellant's claimed invention requires relief from a Th2-dominated disease, there is no requirement in the claims that any particular degree of relief be obtained. Therefore, it appears that the claimed invention is open to any number of doses (effective amounts) as long as they exhibit some degree of relief from a Th2-dominated disease in a patient.

Accordingly, contrary to appellant's assertion, it appears that Bigazzi supports the examiner's finding that Bani provides a reasonable expectation of success. On reflection, all we are left with in support of appellant's position is counsel's arguments, which cannot take the place of objective evidence on the record.


Accordingly, we find no error in the rejection of record. Therefore, we affirm the rejection of claim 1 under 35 U.S.C. § 103. As discussed supra claims 2-5 fall together with claim 1.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED


William F. Smith
Administrative Patent Judge


Joan Ellis
Administrative Patent Judge


Donald E. Adams
Administrative Patent Judge

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